IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 2:22-cv-06263
	)	
ALKEM LABORATORIES LTD.,	)	
	)	
Defendant.	)	

ALKEM LABORATORIES LTD's
ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Alkem Laboratories Ltd. ("Alkem") responds to the First Amended Complaint by Plaintiff Esperion Therapeutics, Inc., ("Esperion") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendant Alkem Laboratories Ltd. ("Alkem"). This action arises out of Alkem's submission of Abbreviated New Drug Application ("ANDA") Nos. 219416 and 219421 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NEXLETOL® and NEXLIZET® prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

ANSWER: Alkem admits that Plaintiffs purport to bring this action for alleged infringement of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, and 11,744,816 under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Alkem admits that it submitted ANDA Nos. 219416 and 219421 in the name of Alkem Laboratories Ltd. Alkem denies any remaining allegations in this paragraph.

THE PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor,

MI 48108.

ANSWER: Alkem lacks knowledge of information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

3. Upon information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having a place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

ANSWER: Admitted.

4. Upon information and belief, Alkem is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Alkem admits that it markets and distributes generic pharmaceutical products in the United States. Alkem denies any remaining allegations in this paragraph.

5. Upon information and belief, Alkem directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

6. Upon information and belief, Alkem works on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

7. Upon information and belief, Alkem prepared and submitted ANDA No. 219416 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Alkem NEXLETOL® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 11,744,816 and 11,926,584. Upon information and belief, Alkem developed the Alkem NEXLETOL® ANDA Product.

ANSWER: Alkem admits that it filed ANDA No. 219416, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLETOL®. Alkem denies any remaining allegations in this paragraph.

8. Upon information and belief, Alkem developed the Alkem NEXLETOL® ANDA Product.

ANSWER: Alkem admits that it filed ANDA No. 219416, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLETOL®. Alkem denies any remaining allegations in this paragraph.

9. Upon information and belief, Alkem is seeking regulatory approval from the FDA to market and sell the Alkem NEXLETOL® ANDA Product throughout the United States, including in New Jersey.

ANSWER: Alkem admits that it filed ANDA No. 219416, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLETOL®. Alkem denies any remaining allegations in this paragraph.

10. Upon information and belief, Alkem intends to obtain approval for Alkem's ANDA No. 219416, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Alkem NEXLETOL® ANDA Product in the United States, including in New Jersey.

ANSWER: Alkem admits that it filed ANDA No. 219416, seeking approval of the ANDA, and

that the Reference Listed Drug in the ANDA is NEXLETOL®. Alkem denies any remaining allegations in this paragraph.

11. Upon information and belief, Alkem prepared and submitted ANDA No. 219421 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET® (the "Alkem NEXLIZET® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

ANSWER: Alkem admits that it filed ANDA No. 219421, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLIZET®. Alkem denies any remaining allegations in this paragraph.

12. Upon information and belief, Alkem developed the Alkem NEXLIZET® ANDA Product.

ANSWER: Alkem admits that it filed ANDA No. 219421, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLIZET®. Alkem denies any remaining allegations in this paragraph.

13. Upon information and belief, Alkem is seeking regulatory approval from the FDA to market and sell the Alkem NEXLIZET® ANDA Product throughout the United States, including in New Jersey.

ANSWER: Alkem admits that it filed ANDA No. 219421, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLIZET®. Alkem denies any remaining allegations in this paragraph.

14. Upon information and belief, Alkem intends to obtain approval for Alkem's ANDA No. 219421, and, in the event the FDA approves that ANDA, to commercially manufacture, use,

offer for sale, sell, and/or import the Alkem NEXLIZET® ANDA Product in the United States, including in New Jersey.

ANSWER: Alkem admits that it filed ANDA No. 219421, seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is NEXLIZET®. Alkem denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 15 states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem admits that this Court generally has subject matter jurisdiction of a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Alkem denies any remaining allegations in this paragraph.

16. This Court has personal jurisdiction over Alkem because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219416 in New Jersey, And intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219416, Alkem, will make, use, import, sell, and/or offer for sale the Alkem NEXLETOL® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 11,744,816, and 11,926,584.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

17. This Court has personal jurisdiction over Alkem because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement

under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219421 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219421, Alkem, will make, use, import, sell, and/or offer for sale the Alkem NEXLIZET® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

18. This Court also has personal jurisdiction over Alkem because, among other things, this action arises from Alkem's actions directed toward New Jersey, and because, upon information and belief, Alkem has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through its registration with the New Jersey Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0400132325; (4) working in concert to develop and market pharmaceutical products, including in New Jersey, with its subsidiary Ascend Laboratories LLC, a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 339 Jefferson Road Suite 101 Parsippany, NJ 07054 USA and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0600158194 (*see* https://www.ascendlaboratories.com/Home/Background and https://www.ascendlaboratories.com/Home/Facility (last visited May 14, 2024)) and (5) working in concert to develop and market pharmaceutical products in New Jersey with its subsidiary Enzene Biosciences, Ltd. (*see* https://www.choosenj.com/news/enzene-expanding-to-new-jersey/ (last visited May 14, 2024)). Alkem has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

19. In addition, this Court has personal jurisdiction over Alkem because, among other things, upon information and belief, (1) Alkem filed its ANDAs for the purpose of seeking

approval to engage in the commercial manufacture, use, sale, or offer for sale of the Alkem NEXLETOL® ANDA Product and the Alkem NEXLIZET® ANDA Product in the United States, including in New Jersey, and (2) upon approval of Alkem's ANDAs, Alkem will market, distribute, offer for sale, sell, and/or import the Alkem NEXLETOL® ANDA Product and the Alkem NEXLIZET® ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Alkem ANDA Products in New Jersey. Upon information and belief, upon approval of Alkem's ANDAs, the Alkem NEXLETOL® ANDA Product and the Alkem NEXLIZET® ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

20. This Court also has personal jurisdiction over Alkem because Alkem regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, C.A. No. 24-cv-04608 (D.N.J. filed Apr. 5, 2024); *GW Research Limited v. Teva Pharmaceuticals, Inc.*, C.A. No. 23-cv-03914 (D.N.J. filed Jul. 21 2023); and *Arbor Pharmaceuticals, LLC v. Alkem Laboratories Ltd.*, C.A. No. 22-cv-00143 (D.N.J. filed Jan. 11, 2022).

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

21. Based on the foregoing systematic and continuous contacts with New Jersey, Alkem is subject to specific personal jurisdiction in New Jersey.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

22. Upon information and belief, Alkem's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Alkem denies that

this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Alkem is not subject to the general jurisdiction of the courts of any state and based on its contacts with the United States as a whole.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

23. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Alkem to litigate this action in this Court, and Alkem is subject to personal jurisdiction in New Jersey.

ANSWER: Alkem does not contest personal jurisdiction in this proceeding. Alkem denies any remaining allegations in this paragraph.

24. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

ANSWER: Paragraph 24 states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest venue in this proceeding. Alkem denies any remaining allegations in this paragraph.

25. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Alkem is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

ANSWER: Paragraph 25 states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest venue in this proceeding. Alkem denies any remaining allegations in this paragraph.

26. Venue is also proper in this Court because, among other things, Alkem has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell the Alkem NEXLETOL® ANDA Product and the Alkem NEXLIZET® ANDA Product in New Jersey; and (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

ANSWER: Alkem does not contest venue in this proceeding. Alkem denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

27. U.S. Patent No. 11,760,714 (the "'714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit A."

ANSWER: Alkem admits that the '714 Patent is entitled "Methods of Making Bempedoic Acid and Compositions of the Same." Alkem admits that Exhibit A purports to be a copy of the '714 Patent. Alkem denies any remaining allegations in this paragraph.

28. Esperion is the assignee of, and holds all rights, title, and interest in the '714 Patent.

ANSWER: Alkem admits that Esperion is an assignee of record of the '714 Patent. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

29. The '714 Patent currently expires on June 19, 2040.

ANSWER: Alkem admits that, according to the Orange Book, the '714 patent will expire on June 19, 2040. Alkem denies any remaining allegations in this paragraph.

30. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

ANSWER: Alkem admits that the '511 Patent is entitled "Methods of Making Bempedoic Acid and Compositions of the Same." Alkem admits that Exhibit B purports to be a copy of the '511 Patent. Alkem denies any remaining allegations in this paragraph.

31. Esperion is the assignee of, and holds all rights, title and interest in the '511 Patent.

ANSWER: Alkem admits that Esperion is an assignee of record of the '511 Patent. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

32. The '511 Patent currently expires on June 19, 2040.

ANSWER: Alkem admits that, according to the Orange Book, the '511 patent will expire on June 19, 2040. Alkem denies any remaining allegations in this paragraph.

33. U.S. Patent No. 10,912,751 (the "'751 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on February 9, 2021. A true and correct copy of the '751 Patent is attached hereto as "Exhibit C."

ANSWER: Alkem admits that the '751 Patent is entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease." Alkem admits that Exhibit C purports to be a copy of the '751 Patent.

Alkem denies any remaining allegations in this paragraph.

34. Esperion is the assignee of, and holds all rights, title and interest in the '751 Patent.

ANSWER: Alkem admits that Esperion is an assignee of record of the '751 Patent and that Esperion conveyed a security interest in this patent to Eiger III SA LLC. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

35. The '751 Patent currently expires on March 14, 2036.

ANSWER: Alkem admits that, according to the Orange Book, the '751 patent will expire on March 14, 2036. Alkem denies any remaining allegations in this paragraph.

36. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit D."

ANSWER: Alkem admits that the '816 Patent is entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease." Alkem admits that Exhibit D purports to be a copy of the '816 Patent. Alkem denies any remaining allegations in this paragraph.

37. Esperion is the assignee of, and holds all rights, title and interest in the '816 Patent.

ANSWER: Alkem admits that Esperion is an assignee of record of the '816 Patent. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations

in this paragraph, and therefore denies them.

38. The ’816 Patent currently expires on March 14, 2036.

ANSWER: Alkem admits that, according to the Orange Book, the ’816 patent will expire on March 14, 2036. Alkem denies any remaining allegations in this paragraph.

39. U.S. Patent No. 11,926,584 (the “’584 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 12, 2024. A true and correct copy of the ’584 Patent is attached hereto as “Exhibit E.”

ANSWER: Alkem admits that the ’584 Patent is entitled “Methods of Making Bempedoic Acid and Compositions of the Same.” Alkem admits that Exhibit E purports to be a copy of the ’584 Patent. Alkem denies any remaining allegations in this paragraph.

40. Esperion is the assignee of, and holds all rights, title and interest in the ’584 Patent.

ANSWER: Alkem admits that Esperion is an assignee of record of the ’584 Patent. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

41. The ’584 Patent currently expires on June 19, 2040.

ANSWER: Alkem admits that, according to the Orange Book, the ’584 patent will expire on June 19, 2040. Alkem denies any remaining allegations in this paragraph.

42. All claims of the ’714, ’511, ’751, ’816, and ’584 Patents are valid, enforceable,

and not expired.

ANSWER: Denied.

ESPERION'S NEXLETOL® PRODUCT

43. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL® and NEXLIZET®.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

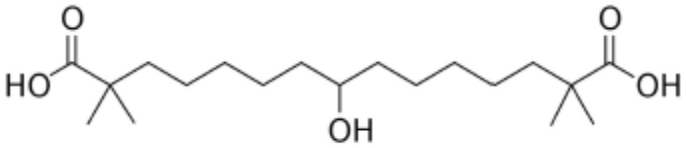
44. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

ANSWER: Alkem admits that, according to records available on the FDA website, Esperion is the holder of New Drug Application ("NDA") No. 211616. Alkem admits that, according to records available on the FDA website, on February 21, 2020, the FDA approved the use of NEXLETOL® in the United States pursuant to NDA No. 211616. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

45. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

46. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER: Alkem admits that, according to records available on the FDA website, Bempedoic Acid is the active ingredient in NEXLETOL®. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

47. The claims of the '714, '511, '816 and '584 Patents cover NEXLETOL®.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

48. The '714, '511, '816, and '584 Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

ANSWER: Alkem admits that the '714, '511, '816, and '584 Patents are listed in the Orange Book in connection with NDA No. 211616. Alkem denies any remaining allegations in this paragraph.

ESPERION'S NEXLIZET® PRODUCT

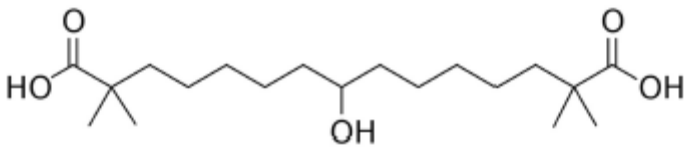
49. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name "NEXLIZET®." Esperion sells NEXLIZET® in the United States pursuant to NDA No. 211617.

ANSWER: Alkem admits that, according to records available on the FDA website, Esperion is the holder of New Drug Application ("NDA") No. 211617. Alkem admits that, according to records available on the FDA website, on February 26, 2020, the FDA approved the use of NEXLIZET® in the United States pursuant to NDA No. 211617. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

50. NEXLIZET® is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET® is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

51. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER: Alkem admits that, according to records available on the FDA website, Bempedoic Acid is one of the active ingredients in NEXLETOL®. Alkem lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

52. Ezetimibe, the other active pharmaceutical ingredients in NEXLIZET®, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

53. The claims of the ’714, ’511, ’751, ’816, and ’584 Patents cover NEXLIZET®.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

54. The ’714, ’511, ’751, ’816, and ’584 Patents have been listed in connection with NEXLIZET® in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”

ANSWER: Alkem admits that the ’714, ’511, ’751, ’816, and ’584 Patents are listed in the Orange Book in connection with NDA No. 211617. Alkem denies any remaining allegations in this paragraph.

ALKEM'S NEXLETOL® ANDA PRODUCT

55. By letter dated April 4, 2024, and received by Esperion via Federal Express no earlier than on April 5, 2024 (the "First NEXLETOL® Notice Letter"), Alkem notified Esperion that Alkem had submitted ANDA No. 219416 to the FDA for a generic version of NEXLETOL®.

ANSWER: Alkem admits that Alkem sent a letter dated April 4, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '511 and '714 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

56. The First NEXLETOL® Notice Letter states that Alkem seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Alkem NEXLETOL® ANDA Product before the expiration of the '714 and '511 Patents. Upon information and belief, Alkem intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Alkem NEXLETOL® ANDA Product promptly upon receiving FDA approval to do so.

ANSWER: Alkem admits that Alkem seeks FDA approval to market the Alkem ANDA Product in the United States. Alkem denies any remaining allegations in this paragraph.

57. By submitting ANDA No. 219416, Alkem has represented to the FDA that the Alkem NEXLETOL® ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

ANSWER: Alkem admits that Alkem seeks FDA approval to market the Alkem ANDA Product in the United States. Alkem denies any remaining allegations in this paragraph.

58. In the First NEXLETOL® Notice Letter, Alkem stated that ANDA No. 219416 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Alkem also contended that the '714 and '511 Patents are invalid,

unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Alkem NEXLETOL® ANDA Product.

ANSWER: Alkem admits that Alkem filed ANDA No. 219416 with a Paragraph IV Certification with respect to the '511 and '714 Patents seeking FDA approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

59. Upon information and belief, Alkem had knowledge of the '714 and '511 Patents at least when it submitted ANDA No. 219416 to the FDA.

ANSWER: Alkem admits that Alkem filed ANDA No. 219416 with a Paragraph IV Certification with respect to the '511 and '714 Patents seeking FDA approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

60. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219416 and prior to the expiration of the '714 and '511 Patents.

ANSWER: Denied.

61. Alkem's First NEXLETOL® Notice Letter only identified invalidity positions with respect to the '714 and '511 Patents and included limited information about the Alkem NEXLETOL® ANDA Product. Alkem's Offer of Confidential Access permitted access only to limited, unspecified portions of Alkem's ANDAs on terms and conditions set by Alkem.

ANSWER: Alkem admits that Alkem filed ANDA No. 219416 with a Paragraph IV Certification with respect to the '511 and '714 Patents seeking FDA approval to market the Alkem ANDA product in the United States. Alkem admits that Alkem sent a letter dated April 4, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the

'511 and '714 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem admits that the April 4, 2024 Notice Letter included an Offer of Confidential Access. Alkem denies any remaining allegations in this paragraph.

62. On or before April 29, 2024, Esperion sent Alkem a proposed revision of the Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219416.

ANSWER: Alkem admits that Plaintiff sent Alkem proposed edits to the Office of Confidential Access. Alkem denies any remaining allegations in this paragraph.

63. Alkem has not provided a substantive response to Esperion's proposed revision of the Offer of Confidential Access and has not provided Esperion with any portions of its ANDA No. 219416 and refused to provide samples of its Alkem NEXLETOL® ANDA Product or components thereof.

ANSWER: Alkem admits that it took Esperion's proposed revisions under advisement and was in the process of considering such revisions when Esperion filed the current civil action. Alkem denies any remaining allegations in this paragraph.

64. Esperion commenced this action by filing a complaint on May 17, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First NEXLETOL® Notice Letter.

ANSWER: Admitted.

65. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 Patent.

ANSWER: Alkem admits that the '584 patent states on its face that it was issued on March 12,

2024. Alkem denies any remaining allegations in this paragraph.

66. On or about April 9, 2024, and within thirty days of issuance of the '584 Patent, Esperion submitted Form 3542 identifying the '584 Patent for listing in the Orange Book for NEXLETOL®.

ANSWER: Alkem admits that the '584 Patent is listed in the Orange Book in connection with NDA No. 211616. Alkem denies any remaining allegations in this paragraph.

67. On information and belief, at some point on or after April 9, 2024, during the pendency of Alkem's ANDA, Alkem provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

ANSWER: Alkem admits that Alkem filed ANDA No. 219416 with a Paragraph IV Certification with respect to the '584 Patent seeking FDA approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

68. On or about March 22, 2024, the FDA approved a new label for NEXLETOL® including for its use to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER: Alkem lacks knowledge of information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

69. On or about April 19, 2024, and within thirty days of the FDA approving a new indication for NEXLETOL®, Esperion submitted Form 3542 identifying the '816 patent for listing in the Orange Book for NEXLETOL®.

ANSWER: Alkem admits that the '816 Patent is listed in the Orange Book in connection with NDA No. 211616. Alkem denies any remaining allegations in this paragraph.

70. On information and belief, at some point on or after April 19, 2024, during the pendency of Alkem's ANDA, Alkem provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '816 Patent.

ANSWER: Alkem admits that Alkem filed ANDA No. 219416 with a Paragraph IV Certification with respect to the '816 Patent seeking FDA approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

71. By letter dated June 7, 2024, and received by Esperion via Federal Express no earlier than on June 10, 2024 (the "Second NEXLETOL® Notice Letter"), Alkem sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 and '816 Patents. In the Second NEXLETOL® Notice Letter, Alkem contended that the '584 and '816 Patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Alkem NEXLETOL® ANDA Product.

ANSWER: Alkem admits that Alkem sent a letter dated June 7, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '584 and '816 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

72. Upon information and belief, Alkem had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 7, 2024.

ANSWER: Alkem admits that Alkem sent a letter dated June 7, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '584 Patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining

allegations in this paragraph.

73. Upon information and belief, Alkem had knowledge of the '816 Patent since at least April 19, 2024, and certainly before June 7, 2024.

ANSWER: Alkem admits that Alkem sent a letter dated June 7, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '816 Patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

74. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219416 and prior to expiration of the '584 and '816 Patents.

ANSWER: Denied.

75. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second NEXLETOL® Notice Letter and prior to Alkem's answer to the original complaint filed May 17, 2024.

ANSWER: Admitted.

ALKEM'S NEXLIZET® ANDA PRODUCT

76. By letter dated April 23, 2024, and received by Esperion via Federal Express no earlier than on April 24, 2024 (the "First NEXLIZET® Notice Letter"), Alkem notified Esperion that Alkem had submitted ANDA No. 219421 to the FDA for a generic version of NEXLIZET®.

ANSWER: Alkem admits that Alkem sent a letter dated April 23, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '511 and '714, '751,

and ’816 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

77. The First NEXLIZET® Notice Letter states that Alkem seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Alkem NEXLIZET® ANDA Product before the expiration of the ’714, ’511, ’751, and ’816 Patents. Upon information and belief, Alkem intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Alkem NEXLIZET® ANDA Product promptly upon receiving FDA approval to do so.

ANSWER: Alkem admits that Alkem sent a letter dated April 23, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem’s ANDA and the ’511 and ’714, ’751, and ’816 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

78. By submitting ANDA No. 219421, Alkem has represented to the FDA that the Alkem NEXLIZET® ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET® and is bioequivalent to NEXLIZET®.

ANSWER: Admitted.

79. In the First NEXLIZET® Notice Letter, Alkem stated that ANDA No. 219421 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’714, ’511, ’751, and ’816 Patents. Alkem also contended that the ’714, ’511, ’751, and ’816 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Alkem NEXLIZET® ANDA Product.

ANSWER: Alkem admits that Alkem sent a letter dated April 23, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem’s ANDA and the ’511 and ’714, ’751, and ’816 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

80. Upon information and belief, Alkem had knowledge of the '714, '511, '751, and '816 Patents at least when it submitted ANDA No. 219421 to the FDA.

ANSWER: Alkem admits that Alkem filed ANDA No. 219421 with a Paragraph IV Certification with respect to the '511, '714, '751, and '816 Patents seeking approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

81. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219421 and prior to the expiration of the '714, '511, '751, and '816 Patents.

ANSWER: Denied.

82. Alkem's First NEXLIZET® Notice Letter only identified invalidity positions with respect to the '714, '511, '751, and '816 Patents and included limited information about the Alkem NEXLIZET® ANDA Product. Alkem's Offer of Confidential Access permitted access only to limited, unspecified portions of Alkem's ANDAs on terms and conditions set by Alkem.

ANSWER: Alkem admits that Alkem sent a letter dated April 23, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '511, '714, '751, and '816 Patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

83. Alkem has not provided Esperion with any portions of its ANDA No. 219421, samples of its Alkem NEXLIZET® ANDA Product, or components thereof.

ANSWER: Alkem admits that the parties have not come to an agreement to exchange any

portions of Alkem's ANDA No. 219421 or samples of Alkem's NEXLIZET® ANDA Product. Alkem denies any remaining allegations in this paragraph.

84. Esperion commenced this action by filing a complaint on May 17, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First NEXLIZET® Notice Letter.

ANSWER: Admitted

85. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 Patent.

ANSWER: Alkem admits that the '584 patent states on its face that it was issued on March 12, 2024. Alkem denies any remaining allegations in this paragraph.

86. On or about April 9, 2024, and within thirty days of issuance of the '584 Patent, Esperion submitted Form 3542 identifying the '584 patent for listing in the Orange Book for NEXLIZET®.

ANSWER: Alkem admits that the '584 Patent is listed in the Orange Book in connection with NDA No. 211617. Alkem denies any remaining allegations in this paragraph.

87. On information and belief, at some point on or after April 9, 2024, during the pendency of Alkem's ANDA, Alkem provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

ANSWER: Alkem admits that Alkem filed ANDA No. 219421 with a Paragraph IV Certification with respect to the '584 Patent seeking approval to market the Alkem ANDA product in the United States. Alkem denies any remaining allegations in this paragraph.

88. By letter dated June 7, 2024, and received by Esperion via Federal Express no earlier than on June 10, 2024 (the "Second NEXLIZET® Notice Letter"), Alkem sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second NEXLIZET® Notice Letter, Alkem contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Alkem NEXLIZET® ANDA Product.

ANSWER: Alkem admits that Alkem sent a letter dated June 7, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '584 Patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

89. Upon information and belief, Alkem had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 7, 2024.

ANSWER: Alkem admits that Alkem sent a letter dated June 7, 2024 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Alkem's ANDA and the '584 Patent, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Alkem denies any remaining allegations in this paragraph.

90. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product immediately and imminently upon approval of ANDA No. 219421 and prior to expiration of the '584 Patent.

ANSWER: Denied.

91. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second NEXLIZET® Notice Letter and prior to Alkem's answer to the original complaint filed May 17, 2024.

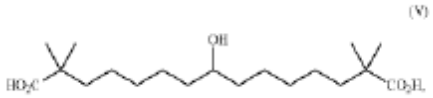
ANSWER: Admitted.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY ALKEM'S NEXLETOL® ANDA PRODUCT

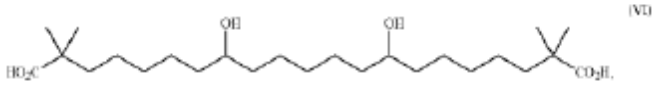
92. Esperion incorporates each of the preceding paragraphs 1-91 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

93. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

ANSWER: Paragraph 93 states a legal conclusion to which no answer is required.

94. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

95. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of

the Alkem NEXLETOL® ANDA Product prior to expiration of the '714 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

96. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

97. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLETOL® Notice Letter, Alkem has knowledge of the '714 Patent and knowledge that its Alkem NEXLETOL® ANDA Product will infringe the '714 Patent.

ANSWER: Denied.

98. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court. 99. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Alkem NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

100. Alkem's infringement is imminent because, among other things, Alkem has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product before the expiration of the '714 Patent.

ANSWER: Denied.

101. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER: Denied.

102. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

103. Unless Alkem is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

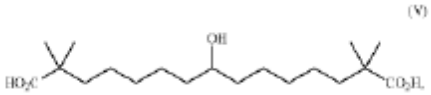
ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY ALKEM'S NEXLIZET® ANDA PRODUCT

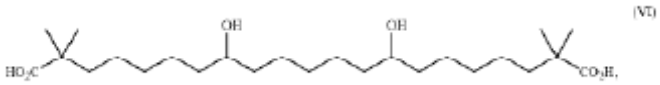
104. Esperion incorporates each of the preceding paragraphs 1-103 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

105. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

ANSWER: Paragraph 105 states a legal conclusion to which no answer is required.

106. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

107. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product prior to expiration of the '714 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

108. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

109. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLIZET® Notice Letter, Alkem has knowledge of the '714 Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '714 Patent.

ANSWER: Denied.

110. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER: Denied.

111. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

112. Alkem's infringement is imminent because, among other things, Alkem has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '714 Patent.

ANSWER: Denied.

113. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER: Denied.

114. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

115. Unless Alkem is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

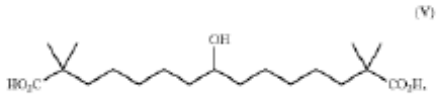
ANSWER: Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY ALKEM'S NEXLETOL® ANDA PRODUCT

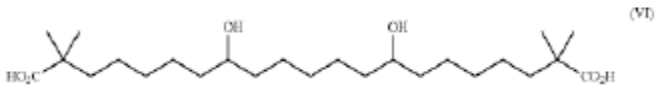
116. Esperion incorporates each of the preceding paragraphs 1-115 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

117. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER: Paragraph 117 states a legal conclusion to which no answer is required.

118. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

119. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product prior to expiration of the '511 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

120. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

121. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLETOL® Notice Letter, Alkem has knowledge of the '511 Patent and knowledge that its Alkem NEXLETOL® ANDA Product will infringe the '511 Patent.

ANSWER: Denied.

122. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER: Denied.

123. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Alkem NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

124. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER: Denied.

125. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

126. Unless Alkem is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

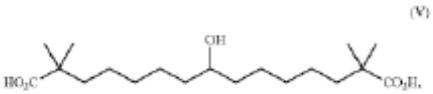
ANSWER: Denied.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY ALKEM'S NEXLIZET® ANDA PRODUCT

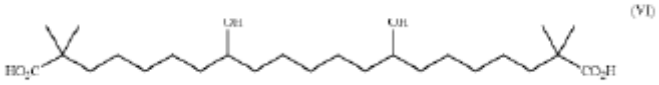
127. Esperion incorporates each of the preceding paragraphs 1-126 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

128. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER: Paragraph 128 states a legal conclusion to which no answer is required.

129. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

130. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product prior to expiration of the '511 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

131. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

132. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLIZET® Notice Letter, Alkem has knowledge of the '511 Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '511 Patent.

ANSWER: Denied.

133. Upon information and belief, Alkem intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER: Denied.

134. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Products is especially made or adapted for use in infringing the '511 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

135. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER: Denied.

136. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

137. Unless Alkem is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,744,816 BY ALKEM'S NEXLETOL® ANDA PRODUCT

138. Esperion incorporates each of the preceding paragraphs 1-137 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

139. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

ANSWER: Paragraph 139 states a legal conclusion to which no answer is required.

140. Upon information and belief, Alkem's NEXLETOL® ANDA Product contains 180 mg of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid.

ANSWER: Admitted.

141. Upon information and belief, 10 mg ezetimibe is commercially available, sold in the United States, and is prescribed by medical practitioners to treat patients.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

142. Upon information and belief, Alkem sells ezetimibe tablets containing 10 mg of ezetimibe in the United States.

ANSWER: Admitted.

143. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

144. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product prior to expiration of the '816 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

ANSWER: Denied.

145. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219416,

Alkem will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Alkem NEXLETOL® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

146. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

ANSWER: Denied.

147. Upon information and belief, Alkem's ANDA No. 219416 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLETOL® ANDA Product.

ANSWER: Alkem admits that Alkem's ANDA No. 219416 includes a proposed package insert that states "Administer 180 mg orally once daily with or without food." Alkem denies any remaining allegations in this paragraph.

148. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, unless enjoined by the Court, and the Alkem NEXLETOL® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

149. Upon information and belief, Alkem's ANDA No. 219416 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third

parties to administer and/or to prescribe the Alkem NEXLETOL® ANDA Product along with 10 mg ezetimibe to lower LDL-C in a human subject who has familial hypercholesterolemia.

ANSWER: Denied.

150. Upon information and belief, following FDA approval of Alkem's ANDA No. 219416, Alkem will promote and/or market the Alkem NEXLETOL® ANDA Product to patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLETOL® ANDA Product along with 10 mg ezetimibe to lower LDL-C in a human subject who has familial hypercholesterolemia.

ANSWER: Denied.

151. Upon information and belief, following FDA approval of Alkem's ANDA No. 219416, medical practitioners and/or third parties will prescribe and/or administer, and patients with familial hypercholesterolemia will take, the Alkem NEXLETOL® ANDA Product along with 10 mg ezetimibe in order to lower LDL-C in the patients.

ANSWER: Denied.

152. Upon information and belief, the use of the Alkem NEXLETOL® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

153. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's Second NEXLETOL® Notice Letter, Alkem has knowledge of the '816 Patent and knowledge that its Alkem NEXLETOL® ANDA Product will infringe the '816 Patent.

ANSWER: Denied.

154. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLETOL® ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

ANSWER: Denied.

155. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Alkem NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

156. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

ANSWER: Denied.

157. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

158. Unless Alkem is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 11,744,816 BY ALKEM'S NEXLIZET® ANDA PRODUCT

159. Esperion incorporates each of the preceding paragraphs 1-158 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

160. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

ANSWER: Paragraph 160 states a legal conclusion to which no answer is required.

161. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

162. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product prior to expiration of the '816 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

ANSWER: Denied.

163. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219421, Alkem will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Alkem NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

164. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

ANSWER: Denied.

165. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET® ANDA Product.

ANSWER: Alkem admits that Alkem's ANDA No. 219421 includes a proposed package insert that states "Administer one tablet (180 mg bempedoic acid and 10 mg ezetimibe) orally once daily with or without food." Alkem denies any remaining allegations in this paragraph.

166. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court, and the Alkem NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

167. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or third parties to administer and/or prescribe the Alkem NEXLIZET® Product to lower LDL-C in a human subject who has familial hypercholesterolemia.

ANSWER: Alkem admits that Alkem's ANDA No. 219421 includes a proposed package insert that states "Bempedoic acid tablet is an adenosine triphosphate-citrate lyase (ACL) inhibitor

indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C." Alkem denies any remaining allegations in this paragraph.

168. Upon information and belief, following FDA approval of Alkem's ANDA No. 219421, Alkem will promote and/or market the Alkem NEXLIZET® ANDA Product to patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET® ANDA Product to lower LDL-C in a human subject who has familial hypercholesterolemia.

ANSWER: Denied.

169. Upon information and belief, following FDA approval of Alkem's ANDA No. 219421, medical practitioners and/or third parties will prescribe and/or administer, and patients with familial hypercholesterolemia will take, the Alkem NEXLIZET® ANDA Product in order to lower LDL-C in the patients.

ANSWER: Denied.

170. Upon information and belief, the use of the Alkem NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

171. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLIZET® Notice Letter, Alkem has knowledge of the '816 Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '816 Patent.

ANSWER: Denied.

172. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLIZET® ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

ANSWER: Denied.

173. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

174. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

ANSWER: Denied.

175. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

176. Unless Alkem is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

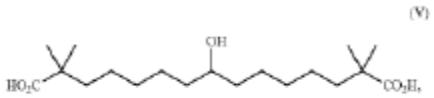
ANSWER: Denied.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY ALKEM'S NEXLETOL® ANDA PRODUCT

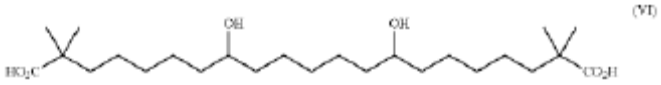
177. Esperion incorporates each of the preceding paragraphs 1-176 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

178. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Paragraph 178 states a legal conclusion to which no answer is required.

179. Alkem's submission of ANDA No. 219416 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

180. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLETOL® ANDA Product prior to expiration of the '584 Patent, and Alkem's

inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER: Denied.

181. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219416, Alkem will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Alkem NEXLETOL® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

182. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219416 is approved by marketing the Alkem NEXLETOL® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER: Denied.

183. Upon information and belief, Alkem's ANDA No. 219416 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLETOL® ANDA Product.

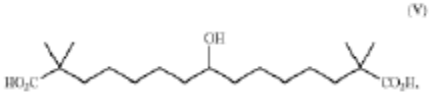
ANSWER: Alkem admits that Alkem's ANDA No. 219416 includes a proposed package insert that states "Administer 180 mg orally once daily with or without food." Alkem denies any remaining allegations in this paragraph.

184. Upon information and belief, upon FDA approval of ANDA No. 219416, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, unless enjoined by the Court, and the Alkem NEXLETOL® ANDA Product will be administered by patients, medical practitioners, and/or other

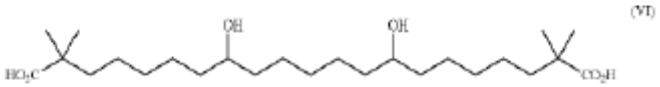
third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

185. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Denied.

186. Upon information and belief, the use of the Alkem NEXLETOL® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

187. Upon information and belief, by virtue of its listing in the Orange Book and identification in Alkem's Second NEXLETOL® Notice Letter, Alkem has knowledge of the '584 Patent and knowledge that its Alkem NEXLETOL® ANDA Product will infringe the '584 Patent.

ANSWER: Denied.

188. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLETOL® ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER: Denied.

189. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219416 is approved, unless enjoined by the Court, because Alkem knows that the Alkem ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Alkem NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

190. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER: Denied.

191. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

192. Unless Alkem is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

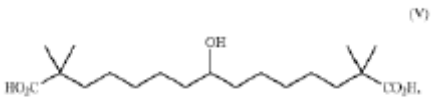
ANSWER: Denied.

COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY ALKEM'S NEXLIZET® ANDA PRODUCT

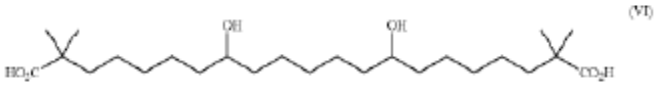
193. Esperion incorporates each of the preceding paragraphs 1-192 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

194. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Paragraph 194 states a legal conclusion to which no answer is required.

195. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

196. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of

the Alkem NEXLIZET® ANDA Product prior to expiration of the '584 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER: Denied.

197. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219421, Alkem will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Alkem NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

198. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER: Denied.

199. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET® ANDA Product.

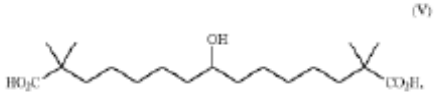
ANSWER: Alkem admits that Alkem's ANDA No. 219421 includes a proposed package insert that states "Administer one tablet (180 mg bempedoic acid and 10 mg ezetimibe) orally once daily with or without food." Alkem denies any remaining allegations in this paragraph.

200. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court, and the Alkem

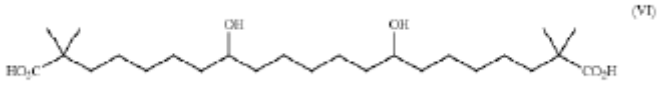
NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

201. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Paragraph 201 states a legal conclusion to which no answer is required.

202. Upon information and belief, the use of the Alkem NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the ’584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

203. Upon information and belief, by virtue of its listing in the Orange Book and identification in Alkem’s Second NEXLIZET® Notice Letter, Alkem has knowledge of the ’584

Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '584 Patent.

ANSWER: Denied.

204. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLIZET® ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER: Denied.

205. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

206. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER: Denied.

207. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

208. Unless Alkem is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

COUNT IX: INFRINGEMENT OF U.S. PATENT NO. 10,912,751 BY ALKEM'S NEXLIZET® ANDA PRODUCT

209. Esperion incorporates each of the preceding paragraphs 1-208 as if fully set forth herein.

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

210. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

ANSWER: Paragraph 210 states a legal conclusion to which no answer is required.

211. Alkem's submission of ANDA No. 219421 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

212. Alkem's commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem NEXLIZET® ANDA Product prior to expiration of the '751 Patent, and Alkem's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

ANSWER: Denied.

213. Upon information and belief, upon FDA approval of Alkem's ANDA No. 219421, Alkem will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the Alkem ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

214. Upon information and belief, Alkem specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219421 is approved by marketing the Alkem NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

ANSWER: Denied.

215. Upon information and belief, Alkem's ANDA No. 219421 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Alkem NEXLIZET® ANDA Product.

ANSWER: Alkem admits that Alkem's ANDA No. 219421 includes a proposed package insert that states "Administer one tablet (180 mg bempedoic acid and 10 mg ezetimibe) orally once daily with or without food." Alkem denies any remaining allegations in this paragraph.

216. Upon information and belief, upon FDA approval of ANDA No. 219421, Alkem intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, unless enjoined by the Court, and the Alkem NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

217. On information and belief, the proposed package insert will include a method of

treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

ANSWER: Denied

218. Upon information and belief, the use of the Alkem NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. 219. Upon information and belief, by virtue of their listing in the Orange Book and identification in Alkem's First NEXLIZET® Notice Letter, Alkem has knowledge of the '751 Patent and knowledge that its Alkem NEXLIZET® ANDA Product will infringe the '751 Patent.

ANSWER: Denied.

220. On information and belief, Alkem is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Alkem NEXLIZET® ANDA Product at least according to Alkem's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.

ANSWER: Denied.

221. Upon information and belief, Alkem intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219421 is approved, unless enjoined by the Court, because Alkem knows that the Alkem NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the Alkem NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

222. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

ANSWER: Denied.

223. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Alkem's making, using, offering to sell, selling, and/or importing the Alkem NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

224. Unless Alkem is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Alkem denies that Plaintiffs are entitled to any relief described in the section of the Complaint entitled "Prayer for Relief," and deny that Plaintiff are entitled to any relief whatsoever. Alkem further denies any allegation in the Complaint not specifically admitted above.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Alkem asserts the following affirmative defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST AFFIRMATIVE DEFENSE

The claims of the '714 patent are invalid for failure to satisfy one or more of the

conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Alkem's Notice Letters dated April 4, 2024 and April 23, 2024.

SECOND AFFIRMATIVE DEFENSE

The claims of the '511 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Alkem's Notice Letters dated April 4, 2024 and April 23, 2024.

THIRD AFFIRMATIVE DEFENSE

The claims of the '751 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Alkem's Notice Letter dated April 23, 2024.

FOURTH AFFIRMATIVE DEFENSE

The claims of the '816 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Alkem's Notice Letters dated April 23, 2024 and June 7, 2024.

FIFTH AFFIRMATIVE DEFENSE

The claims of the '584 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Alkem's Notice Letters dated June 7, 2024.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

RESERVATION OF DEFENSES

Alkem reserves the right to assert any and all additional defenses and counterclaims that discovery may reveal.

Dated: July 24, 2024

/s/ Rebekah Conroy

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